**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Before the Board of Patent Appeals and Interferences**

**In re the Application of**

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| **Inventor** | **:** | **David Becker et al.** |
| **Application No.** | **:** | **10/599,306** |
| **Filed** | **:** | **September 25, 2006** |
| **For** | **:** | **ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING** |

# APPEAL BRIEF

**On Appeal from Group Art Unit 3768**
**Examiner Vani Gupta**

**W. Brinton Yorks, Jr.**

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## I. REAL PARTY IN INTEREST

The real party in interest is Koninklijke Philips Electronics N.V., Eindhoven, The Netherlands by virtue of an assignment recorded September 25, 2006 at reel 018299, frame 0205.

## II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

## III. STATUS OF CLAIMS

This application was originally filed with Claims 1-20. Following several Office actions and the cancellation of Claim 3, Claims 1-2 and 4-20 now stand finally rejected by an Office action mailed on April 28, 2011. A Notice of Appeal was timely filed on July 26, 2011. The claims being appealed are Claims 1-2 and 4-20.

## IV. STATUS OF AMENDMENTS

No amendments were filed in response to the final rejection mailed April 28, 2011.

## V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Ultrasound probes which are to be inserted into a body cavity to scan organs of the urinary or reproductive systems are configured with a handle and the ultrasound transducer located at the end of an elongated shaft. The transducer can scan the interior of the body in one of two ways: either electronic steering of beams from a fixed transducer or mechanical sweeping of a movable transducer. The present invention is a mechanically swept probe, in which a motor in the handle actuates a drive mechanism to mechanically sweep a pivotally mounted array transducer located at the distal end of the probe. For mechanically swept probes, the transducer must be located in a liquid-filled compartment which permits transducer movement while coupling ultrasound energy between the body and the transducer. Ultrasound at diagnostic imaging frequencies does not travel through air. A problem with such

probes is that the fluid compartment can be sizeable, extending at times into the shaft of the probe. A sizeable fluid compartment must be filled with a substantial amount of fluid which has weight, and is located at the distal end of the probe. The distally-located weight of the transducer assembly and liquid causes the center of gravity of the probe to be located forward of the handle, which adversely affects manipulation and use of the probe.

The present invention overcomes this difficulty by constraining the fluid to a rigidly dimensioned transducer mount compartment at the distal end of the shaft, with only a small volume compensation balloon extending into the shaft behind the transducer assembly. Constraining the fluid in this manner causes the center of gravity of the probe to be located in the handle, which enables easier manipulation and use of the probe. Figure 3 of the Specification is presented below to illustrate one embodiment of the present invention.

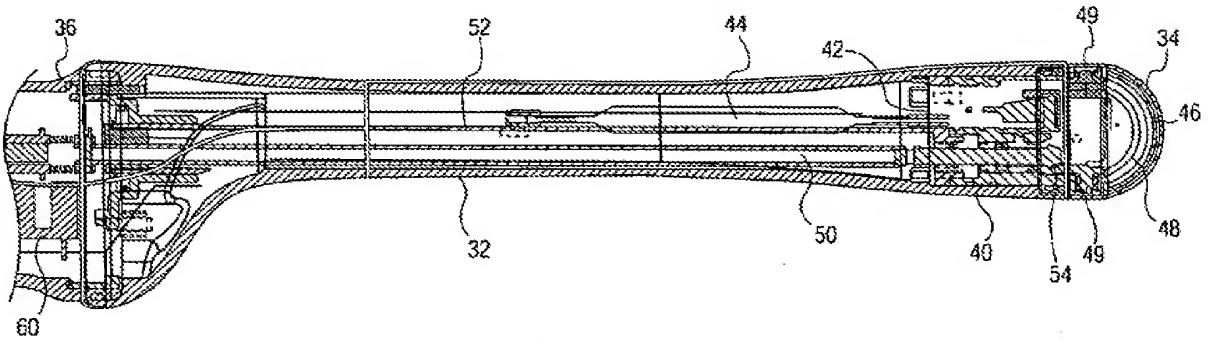



FIG. 3

Comparing independent Claim 1 to the drawings and specification, it is seen that the claim is supported by reference numerals (#) of the drawings and the specification text (pg., ln) as follows:

1. An ultrasonic intracavity probe for scanning a volumetric region from within the body comprising:

a handle section {#36; pg. 4, ln 11-13} to be held during use of the probe; and

a shaft section {#32; pg. 4, ln 14-19} having a distal end which is to be inserted into a body cavity during use of the probe;

a pivotally mounted array transducer {#46; pg. 4, ln 19-29} located in a rigidly dimensioned compartment {#34, #40; pg. 4, ln 14-19; pg 6, ln 5-25} at the distal end of the shaft section;

a motor {#60; pg. 4, ln 29-32} located in the handle section;

a drive mechanism {#50; pg. 4, ln 29-32} coupled to the motor and the array transducer which acts to move the array transducer during scanning; and

a liquid bath constrained to the shaft section to the exclusion of the handle section and located in the compartment at the distal end of the shaft {pg. 6, ln 5-27}, a portion of which is located between the array transducer and the distal end of the shaft during scanning,

wherein the center of gravity of the probe is located in the handle section {pg. 6, ln 27-35}.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether Claims 1, 2, 4-10, and 17-20 were improperly rejected under 35 U.S.C. §103(a) as being obvious over US Pat. 5,178,150 (Silverstein et al.) in view of U.S. Pat. 4,007,735 (Magnusson).

B. Whether Claims 11-16 were improperly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and Magnusson as applied to Claim 1, and further in view of US Pat. 6,315,710 (Bushek et al.).

## VII. ARGUMENT

### *A. Whether Claims 1, 2, 4-10, and 17-20 were improperly rejected under 35 U.S.C. §103(a) as being obvious over US Pat. 5,178,150 (Silverstein et al.) in view of U.S. Pat. 4,007,735 (Magnusson).*

Amended Claim 1 describes a novel ultrasonic intracavity probe for scanning a volumetric region from within the body. The probe has improvements which ease the manipulation and control of the device.

As is commonly known, when an ultrasonic imaging probe has a transducer which is swept or oscillated inside the probe to scan a body, an acoustic coupling liquid must be located between the transducer and the surrounding acoustic window

of the probe to couple ultrasound between the acoustic window and the transducer, as ultrasound does not travel through air without severe attenuation. The common way to do this is to immerse the moving transducer in a liquid such as mineral oil or water.

But a liquid is heavy and adds weight to the probe, a problem which is compounded when the probe is an elongated probe such as an intracavity probe. In that case, the liquid not only adds weight but, by the necessity of being at the end of the probe where the transducer is located, undesirably shifts the center of gravity toward the distal (transducer) end of the probe, making the probe more difficult to manipulate and control. The problem is further compounded when the probe is designed for 3D imaging, as a 3D imaging array transducer must be used and not the smaller single piston or annular array transducers which are used in 2D imaging.

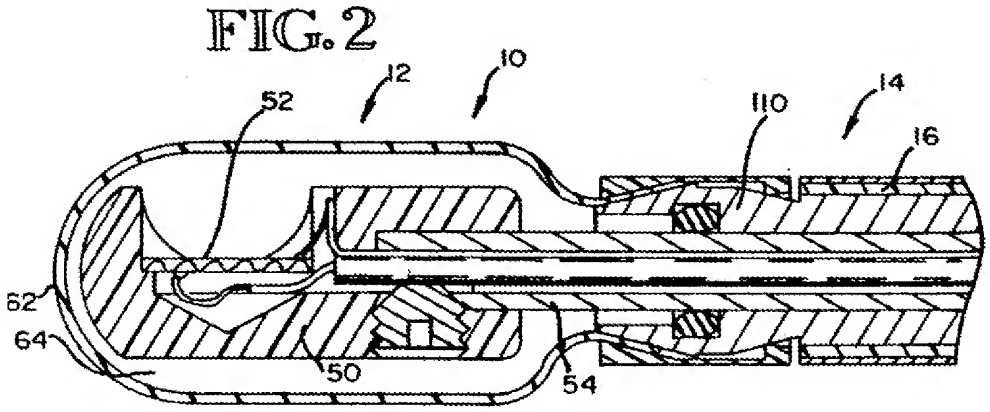
As stated at the bottom of Page 5 of the Specification, some of the probes of the prior art such as the one described in the Silverstein et al. patent locate the liquid couplant in an elastomeric bag, which is bulky (Col. 5, Line 64 of Silverstein et al.) and can tear or rupture, posing a hazard to the patient in whose body the probe is used.

The present inventors have overcome these obstacles by confining the liquid to a rigidly dimensioned compartment in the shaft of an intracavity probe where it provides acoustic coupling between the array transducer and the acoustic window at the distal end of the probe, and still keeps the center of gravity in the handle of the probe. Confining the liquid to the shaft also avoids complications of the liquid passing around or through the motor of the probe in the handle section of the probe, and the rigid compartment is not subject to tearing or rupture and thus does not pose a hazard to the patient.

Silverstein et al. describe a miniature ultrasound imaging probe which includes a probe tip 12 mounted at the distal end of a flexible catheter 14. The probe tip includes a transducer body 50 (having a rounded end 70) mounted on the distal end of a distal actuating rod 54 with the transducer body carrying an ultrasound transducer 52. A flexible bag 62 filled with an acoustic coupling fluid 64 is mounted at the distal end of the catheter 14. The bag 62 surrounds the transducer body 50 to isolate it from the external environment and retain the acoustic coupling fluid 64.

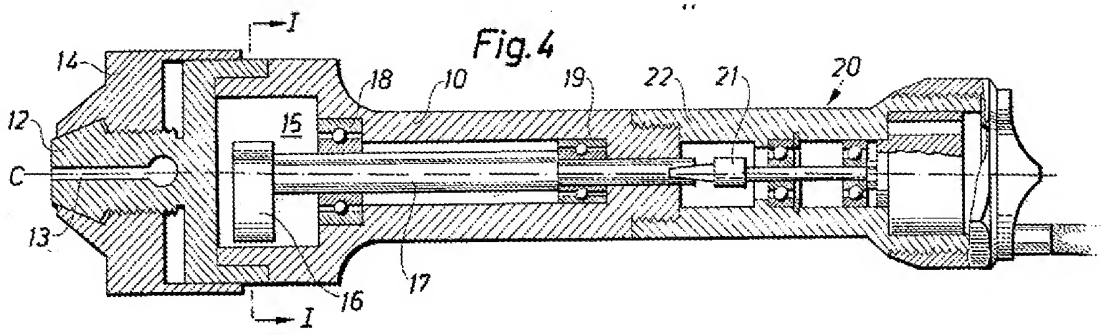
When the probe is to be inserted through a narrow passage, the proximal actuating rod 54 is advanced into the catheter 14 to extend the transducer body 50 against the flexible bag 62. As a result, the bag elongates and its width is reduced. Silverstein et al. Abstract and Figure 2.

**Silverstein et al. Fig. 2**




Magnusson describes a pneumatic cervical vibrator wherein the center of gravity of the vibrator is relatively close to the end of the holder where a pneumatic motor 20 is placed. The motor 20 drives a cam-type vibrating body 16 via a shaft 17. See Magnusson Fig. 4 reproduced below.

**Magnusson Fig. 4**



As grounds for rejecting Claim 1, it is contended that Silverstein et al. disclose each of the limitations, including a pivotally mounted array transducer (52) located in a rigidly dimensioned liquid-filled compartment, but does not specifically suggest that the center of gravity is located in the handle. It is further contended that Magnusson may be properly combined with Silverstein et al. to remedy the deficiency, Magnusson teaching a medical probe with the center of gravity in the probe. Appellant traverses this grounds for rejection for a number of reasons.

*The Silverstein et al. and Magnusson combination fails to teach the "rigidly dimensioned compartment" limitation.*

Claim 1 recites that the transducer is located in a rigidly dimensioned compartment at the distal end of the shaft section, and that the liquid bath is located in the compartment.

It is contended that the Silverstein et al. transducer body 50 with its curved portion 70 teach the Claim 1 rigidly dimensioned compartment. Final Action Paragraph 2. Appellant respectfully traverses.

Appellant respectfully submits that Silverstein et al. clearly teach a transducer 52 which resides on, and not in, transducer body 50. Silverstein et al. Fig. 2, 4 and Col.5 ln.49-52 ("...probe tip 12 includes a transducer body 50 carrying an ultrasound transducer 52.") Neither transducer 52 nor liquid bath 64 are "in" transducer body 50, 70 by any reasonably broad interpretation of the limitation.

Nor can the Silverstein et al. flexible bag 62 be considered a rigidly dimensioned compartment. The Silverstein et al. Abstract states:

> A flexible bag [62] filled with an acoustic coupling fluid is mounted at the distal end of the catheter. The bag surrounds the transducer body [50] to isolate it from the external environment and retain the acoustic coupling fluid. When the probe is to be inserted through a narrow passage the proximal actuating rod [54] is advanced into the catheter to extend the transducer body against the flexible bag. As a result, **the bag elongates and its width is reduced**. When the probe is to be used for imaging, the proximal actuating rod is retracted to withdraw the transducer body away from the bag and **allow the bag to expand radially**...."

As this description plainly states, the liquid compartment is not "rigidly dimensioned" as recited in Claim 1 of the present application. To the contrary, Silverstein et al. wants the bag to stretch and contort as the catheter is manipulated through the body and used for scanning.

Magnusson fails to remedy the Silverstein et al. deficiency. Magnusson teaches none of a rigidly dimensioned compartment at a distal end of a shaft section, a transducer, or a liquid bath at all.

*The Silverstein et al. and Magnusson combination fails to teach the "array transducer" limitation.*

Silverstein et al. teach only a single transducer 52 which is affixed to a body 50 which in turn is affixed to shaft 54. See Silverstein et al. Fig. 2. There is no suggestion within Silverstein et al. that transducer 52 is or could be an array transducer.

Magnusson is not concerned with an ultrasonic probe at all, so it cannot remedy the Silverstein et al. deficiency.

*The Silverstein et al. and Magnusson combination fails to teach the "pivotally mounted" limitation in the array transducer or any other device.*

Silverstein et al. teach a transducer 52 that is rigidly fixed to body 50 and shaft 54 within catheter 14. Appellant respectfully submits that the "rotating, reciprocating, or moving the catheter 14" comment in Silverstein et al. is directed to manually changing the viewing position of transducer 52 with shaft 54 and does not describe the movement of a pivotally-mounted transducer. See Silverstein et al. Column 4 lines 55-58. Indeed, an inspection of the Silverstein et al. structure clearly indicates that the transducer is not pivotally mounted. Id. Fig. 2.

Furthermore, Appellant respectfully points out that one feature of a pivotally-mounted a transducer is that it allows for sweeping an image plane in front of the probe. Specification page 4 lines 25-29. There is no suggestion within Silverstein et al of any such forward-looking feature. Thus, there is no teaching, suggestion, or motivation to modify the Silverstein et al. device with a pivot mount.

Magnusson fails to remedy the lack of a pivotally mounted transducer in Silverstein et al. Magnusson teaches no transducer at all. Nor does Magnusson suggest any component which is pivotally-mounted.

*The combination of Magnusson with Silverstein et al. is improper.*

The Magnusson patent describes a pneumatic cervical vibrator. Magnusson was cited because it states that the center of gravity of the vibrator is relatively close to the end of the holder where the pneumatic motor is placed. Appellant respectfully submits that Magnusson, having nothing to do with ultrasound, is of a non-analogous art and would not be considered by one skilled in the art of ultrasonic probe design.

Attached herewith is a declaration from Dr. John Fraser, who has designed and developed ultrasound probes and transducers for over 38 years. Dr. Fraser makes plain the fact that no one skilled in the art of ultrasound probes and transducers, the subject of the present application, would consider the Magnusson patent and cervical vibrator to be relevant to ultrasound. In the present invention the inventors faced the challenge of reducing the capacity of the rigidly dimensioned fluid compartment at the tip of the probe shaft to as great a degree as practical so as to make the probe more maneuverable and controllable by the sonographer. The Magnusson vibrator has no transducer, no rigidly dimensioned fluid compartment, no liquid bath to couple ultrasound from a transducer to a patient. Whereas the objective of the Magnusson device is to vibrate the tip of the device while reducing the vibrations felt by the operator's hand, an ultrasonic probe seeks to avoid such vibrations. Thus, the two arts are entirely different.

As the Fraser declaration makes clear, the non-analogous Magnusson patent is irrelevant to an ultrasound probe designer and thus cannot be combined with the Silverstein et al. patent to render the claimed invention unpatentable.

Appellant respectfully submits therefore that Silverstein et al. in view of Magnusson fail to disclose or suggest each limitation of Claim 1 as required for a finding of 35 U.S.C. §103 obviousness. Appellant respectfully requests

reconsideration and allowance of Claim 1. Appellant also requests reconsideration and allowance of Claim 2 and Claims 4-20 by reason of their dependency on Claim 1.

***B. Whether Claims 11-16 were improperly rejected under 35 U.S.C. §103(a) as unpatentable over Silverstein et al. and Magnusson as applied to Claim 1, and further in view of US Pat. 6.315.710 (Bushek et al.).***

Claims 11-16 further limit independent Claim 1 by describing embodiments including a transducer mount assembly.

Silverstein et al. and Magnusson are described above.

Bushek et al. teach an ear implantable hearing assistance system which includes a vibrating auditory element and a transducer that senses or provides such mechanical vibrations. A screw and spring mechanism obtains the desired coupling force between the transducer and the auditory element.

It is contended that Bushek et al. remedy the deficiencies of Silverstein et al. and Magnusson by teaching the transducer mount limitations of Claims 11-16. Appellant respectfully traverses.

Bushek et al. fail to disclose or suggest the limitations in amended Claim 1 which are missing from the Silverstein et al. and Magnusson references. In particular, Bushek et al. fail to disclose or suggest any array transducer, any pivotally mounted transducer, and any rigidly dimensioned compartment, as recited in Claim 1. And regarding Claim 14, Bushek et al. fail to disclose or suggest any transducer cradle which is tapered.

Appellant submits therefore that Silverstein et al. in view of Magnusson and Bushek et al. fail to disclose or suggest each limitation of Claims 11-16 as required for a finding of 35 U.S.C.§103 obviousness. Appellant respectfully requests reconsideration and allowance of Claims 11-16.

## VIII. CONCLUSION

Based on the law and the facts, it is respectfully submitted that Claims 1, 2 and 4-19 are not rendered obvious by Silverstein et al. in view of Magnusson, and that Claims 11-16 are not rendered obvious by Silverstein et al. in view of Magnusson and Bushek et al. Accordingly, it is respectfully requested that this Honorable Board reverse the grounds of rejection of these claims stated in the April 28, 2011 Office action being appealed.

Respectfully submitted,

DAVID BECKER ET AL.

By: /W. Brinton Yorks, Jr./
W. Brinton Yorks, Jr.
Reg. No. 28,923

## APPENDIX A: CLAIMS APPENDIX

The following Claims 1-2 and 4-20 are the claims involved in the appeal.

1. (previously presented) An ultrasonic intracavity probe for scanning a volumetric region from within the body comprising:

a handle section to be held during use of the probe; and

a shaft section having a distal end which is to be inserted into a body cavity during use of the probe;

a pivotally mounted array transducer located in a rigidly dimensioned compartment at the distal end of the shaft section;

a motor located in the handle section;

a drive mechanism coupled to the motor and the array transducer which acts to move the array transducer during scanning; and

a liquid bath constrained to the shaft section to the exclusion of the handle section and located in the compartment at the distal end of the shaft, a portion of which is located between the array transducer and the distal end of the shaft during scanning,

wherein the center of gravity of the probe is located in the handle section.

2. (original) The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly located in the distal end of the shaft section, the array transducer being pivotally mounted to the transducer mount assembly,
wherein the liquid bath is located within the transducer mount assembly.

3. (canceled)

4. (previously presented) The ultrasonic intracavity probe of Claim 2, wherein the transducer mount assembly has a proximal termination within one and one-half inches of the terminus of the distal end of the shaft section.

5. (original) The ultrasonic intracavity probe of Claim 4, wherein 90% of the liquid bath is contained within the transducer mount assembly.

6. (original) The ultrasonic intracavity probe of Claim 1, wherein the liquid bath has a volume of less than 25 cc of liquid.

7. (original) The ultrasonic intracavity probe of Claim 6, wherein the liquid bath has a volume of less than 10 cc of liquid.

8. (original) The ultrasonic intracavity probe of Claim 7, wherein the liquid bath has a volume of approximately 6 cc of liquid.

9. (original) The ultrasonic intracavity probe of Claim 1, wherein 90% of the liquid bath is located in the most distal 25% of the length of the shaft section.

10. (original) The ultrasonic intracavity probe of Claim 9, wherein the liquid bath has a volume of less than 10 cc of liquid.

11. (original) The ultrasonic intracavity probe of Claim 1, further comprising a transducer mount assembly having a main body and located in the distal end of the shaft section, the array transducer being pivotally mounted to the transducer mount assembly, the main body of the transducer mount assembly being formed of a material which is lighter than stainless steel.

12. (original) The ultrasonic intracavity probe of Claim 11, wherein the array transducer is pivotally mounted to the transducer mount assembly by a transducer cradle,

wherein the transducer cradle is made of a material which is lighter than stainless steel.

13. (original) The ultrasonic intracavity probe of Claim 12, wherein the transducer cradle includes a solid body located behind the array transducer which displaces volume in the transducer mount assembly that would otherwise be occupied by liquid.

14. (original) The ultrasonic intracavity probe of Claim 12, wherein the transducer cradle is tapered so as to pass more easily through the liquid bath.

15. (previously presented) The ultrasonic intracavity probe of Claim 11, wherein the transducer mount assembly includes wear surfaces which are made of stainless steel.

16. (original) The ultrasonic intracavity probe of Claim 15, wherein the wear surfaces are part of the drive mechanism.

17. (original) The ultrasonic intracavity probe of Claim 11, wherein the weight of the probe is less than 400 grams.

18. (original) The ultrasonic intracavity probe of Claim 17, wherein the weight of the probe is less than 300 grams.

19. (original) The ultrasonic intracavity probe of Claim 18, wherein the weight of the probe is approximately 250 grams.

20. (original) The ultrasonic intracavity probe of Claim 18, wherein the only components of the shaft which are made of a material at least equal to the density of stainless steel are components of the drive mechanism.

## APPENDIX B: EVIDENCE APPENDIX

Declaration of Dr. John D. Frasier appears on the following two pages:

US040173

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David Becker et al.

Art Unit: 3768

Serial No.: 10/599,306

Examiner: Vani Gupta

Filed : September 25, 2006

For : ULTRASONIC INTRACAVITY PROBE FOR 3D IMAGING

Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 CFR §1.132

Dear Sir:

I, John Douglas Fraser do hereby declare as follows:

1. I am a Principal Scientist employed by Philips Healthcare in their ultrasound research and design department in Bothell, Washington. For the past 38 years I have worked in the research, development and design of ultrasound imaging probes and transducers for ultrasound imaging probes, including the past twelve years with Philips Healthcare.

2. I hold a bachelor of science degree in applied physics from the California Institute of Technology and a PhD degree from Stanford University in applied physics, where my thesis topic was "The Design of Efficient, Broadband Ultrasonic Transducers." I am an inventor or co-inventor on 18 issued U.S. patents and have over a dozen patent applications pending in the United States and other countries.

3. I am familiar with the intracavity ultrasound probe of David Becker et al. which is the subject of this patent application. I have reviewed US Pat. 4,007,735 of Magnusson which was cited in this patent application. In my opinion, a designer of intracavity ultrasound probes would find no use for the information in the Magnusson patent and would not consider it relevant to intracavity ultrasound probes. The purpose of an intracavity ultrasound probe such as that developed by Becker et al. is to oscillate an ultrasound transducer back and forth to image the region in front of the transducer. The purpose of the Magnusson cervical vibrator is to deliver physical vibrations at the tip of a vibrating tool. Such vibrations are to be avoided in the design of an ultrasound imaging probe. One of the challenges faced by Becker et al. was to reduce the fluid compartment of an ultrasound probe to as great a degree as practical so that the weight at the tip of the probe would be low, making the probe easier to manipulate during an imaging exam. The challenge which Magnusson said he was facing was to reduce the vibratory sensation to the hand of someone holding a cervical vibrator. These objectives are entirely different. The Magnusson cervical vibrator is pneumatically driven, which is a drive technique we would not consider for an ultrasound probe. As I look at the drawings of the Magnusson cervical vibrator I see no components that I would find useful for an ultrasound imaging probe.

4. In conclusion and following from the above, it is my opinion that one skilled in the art of ultrasound imaging probe design or development would not consider the Magnusson patent or cervical vibrator relevant or useful to ultrasound imaging probes.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

John Douglas Fraser

Date: March 24, 2011

## APPENDIX C: RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.